

## REMARKS

Claim 4 has been cancelled and its limitations incorporated into Claim 1. Claims 1, 2 and 5-7 have been amended. Claims 1, 2 and 5-7 are now pending in the present application. Support for the amendment to claims 1 and 6 may be found in the specification at page 6, last line to page 7, line 16 and in Example 3, pages 24-25. Since these amendments do not add new matter, entry thereof is respectfully requested. Reconsideration and withdrawal of the present rejections in view of the comments presented herein are respectfully requested.

### Rejections under 35 U.S.C. § 112, first paragraph

Claims 1, 2 and 4-7 were rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. The Examiner noted that the specification, while being enabling for treating hyperlipidemia or liver disorders such as cirrhosis and hepatitis, allegedly does not reasonably provide enablement for preventing all liver and gallbladder disorders. Although Applicants do not agree with the rejection, claims 1 and 6 as amended no longer recite treatment and/or prevention of hyperlipidemia or gallbladder/liver disorders, and instead recite methods of reducing triglyceride levels, which are clearly enabled by the specification. See specification at page 6, last line to page 7, line 16 and in Example 3, pages 24-25.

In view of the comments provided above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

### Rejection under 35 U.S.C. § 112, second paragraph

Claims 1, 2 and 4-7 were rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite, for failing to set forth any steps in the method/process. Claims 1 and 6 as amended recite a positive method step (administering a functional beverage/composition comprising the recited catechins) to an individual.

Claims 1, 2 and 4-7 were rejected as allegedly being indefinite based on recitation of "isomers" in claims 1 and 6. The Examiner noted that it was not clear if this term referred to structural isomers or stereoisomers. Claims 1 and 6 as amended recite "stereoisomers." Methyl catechins are pairs of stereo isomers that are non-superimposable mirror images of each other, and which include asymmetrical carbon atoms.

Claims 1 and 6 were rejected as allegedly being indefinite, since it was unclear why the listed teas were in quotations. Claims 1 and 6 as amended no longer contain quotation marks.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

**Rejection under 35 U.S.C. § 101**

Claims 1, 2 and 4-7 were rejected under 35 U.S.C. § 101, because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper process claim under 35 U.S.C. § 101. Claims 1 and 6 as amended recite a positive method step (administering a functional beverage/composition comprising the recited catechins) to an individual. In view of the amendments, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 101.

**Rejections under 35 U.S.C. § 103(a)**

Claims 1, 2 and 4-7 were rejected as allegedly being unpatentable over JP2000-060427A abstract (Derwent Acc-No: 2000-249590) in view of JP 2001-253879 abstract, and in further view of Iwasaki et al. (US 7,014,876). Claims 1, 2 and 4-7 were also rejected as allegedly being unpatentable over JP 2000-159670 (abstract) in view of Iwasaki et al. (US 7,014,876). The Examiner contends that it would have been obvious to utilize a drink containing catechin or O-methylated catechins to improve liver function, and to try/utilize catechins or O-methylated catechins found in black tea in a health drink, such as one to improve the function of the liver in the amounts of Iwasaki et al.

The pending claims have been amended to recite a method of reduction of triglyceride levels by administering a beverage or composition comprising the recited catechins and derived from the recited list of tea leaves. Although the limitation relating to the composition being "derived from" the particular tea leaves is technically a product-by-process limitation, the limitation does limit the product in that the specific catechins present in the composition would depend on the source of tea leaves from which they are derived.

None of the references cited by the Examiner disclose or suggest methods of reducing triglyceride levels by administering a beverage or composition comprising the recited catechins. JP2000-060427A discloses that a black tea beverage containing epigallocatechin has a hepatic function amelioration effect. JP2001-253879 and JP 2000-159670 disclose that catechins have antiallergic activity. Iwasaki et al. disclose a beverage containing catechins for health enhancement. Thus, none of the cited references teach or disclose that catechins lower

triglyceride levels. Thus, the claims cannot be obvious in view of these references, either alone or in combination.

In the Office Action at page 11, the Examiner stated that: "The instant claims do not provide any steps, and therefore the O-methylated catechins containing beverage of JP 2000-159670 encompasses the beverage of the instant claims and is capable of the same method." Since the claims now recite a method step, it is clear that JP 2000-159670 neither discloses nor suggests such methods.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

**Further Evidence of Nonobviousness**

In the accompanying Information Disclosure Statement, Applicants have provided a printout from the Now Foods website, which purports to indicate that "Previous research has shown that four weeks of tea consumption . . . lowers blood levels of . . . triglycerides." This printout does not qualify as prior art with respect to the present application, as it indicates a publication date of December 12, 2006, after the filing date of the present application. However, the printout cites three references, numbered 10-12 as support for the foregoing statement. Copies of these three references are also included in the accompanying Information Disclosure Statement.

Applicants wish to note that none of the three references cited in the Now Foods printout actually support the statement made in the printout. In fact, the references referred to in the printout teach away from the presently claimed invention. A copy of the reference published in November 2006, which is summarized in the printout, is also included in the Information Disclosure Statement. In accordance with the statement in the printout, this reference concludes that "no significant differences were observed for triglycerides" in patients consuming tea. Additionally, the reference numbered 11 in the printout also teaches away from the invention. This reference is referred to in the printout as authored by H. Chen et al., but is properly cited as "Maron et al." in the accompanying Information Disclosure Statement. The Maron et al. reference concluded that "triglycerides rose  $2.6\% \pm 3.5\%$  ( $P=.47$ ) in the tea extract group." Maron et al. at page 1450, second column.

The reference numbered 10 in the printout is referred to therein as authored by Pal, but is properly cited as "Bursill et al." in the accompanying Information Disclosure Statement. In

addition, the reference numbered 12 is referred to as being authored by Q.P. Dou in the printout, but is properly cited as "Kuhn et al." in the accompanying Information Disclosure Statement. The Bursill et al. and the Kuhn et al. references disclose the effect of green tea/catechins on LDL receptor and cholesterol levels. Neither reference provides information on triglyceride levels.

Thus, the references cited in the Information Disclosure Statement show that prior art testing of the effect of green tea/catechins on triglyceride levels resulted in either a small increase or no effect on triglyceride levels. Applicants have unexpectedly discovered that administration of the recited catechins derived from the recited forms of tea leaves can decrease triglyceride levels. This unexpected discovery is further evidence of the patentability of the claimed invention.

### CONCLUSION

Applicants submit that all claims are in condition for allowance. However, if minor matters remain, the Examiner is invited to contact the undersigned at the telephone number provided below. If any additional fees are required, please charge these to Deposit Account No. 11-1410. Should there be any questions concerning this application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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